



AP/IFW

[10121/03501]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Wells et al.
Serial No. : 10/674,512
Filed : September 30, 2003
For : Through the Scope Tension Member Release Clip
Art Unit : 3739
Examiner : Matthew J. Kasztejna

Mail Stop: Appeal Brief-Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

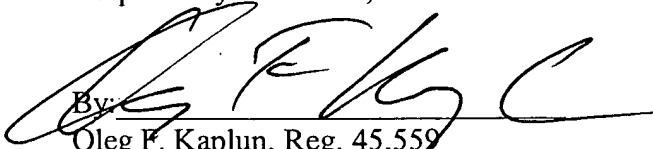
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By: Oleg F. Kaplun, Reg. No. 45,559	Date: November 3, 2005

TRANSMITTAL

In response to the Notice of Appeal filed August 10, 2005 and the Advisory Action dated August 3, 2005, transmitted herewith please find an Appeal Brief (in triplicate) for filing in the above-identified application. Applicants hereby request a one-month extension. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of \$620.00 (PTO-Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: November 3, 2005

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PATENT
Attorney Docket No.: 10121 - 03501

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)	
)	
Brian Keith Wells et al.)	
)	
Serial No.: 10/674,512)	Group Art Unit: 3739
)	
Filed: September 30, 2003)	Examiner: Matthew J. Kasztejna
)	
For: THROUGH THE SCOPE TENSION)	Board of Patent Appeals and
MEMBER RELEASE CLIP)	Interferences

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed on August 10, 2005, and pursuant to 37

C.F.R. § 41.37, Appellants present in triplicate an appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1-5, 10, 11, 15, 17, and 18 in the Final Office Action dated May 11, 2005. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Scimed Life Systems, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1-5, 10, 11, 15, 17, and 18 have been rejected in the final Office Action. Claims 6-9, 12-14, 16, and 19-27 have been objected to as being dependent upon a rejected base claim. Claims 28-36 have been allowed. The final rejection of claims 1-5, 10, 11, 15, 17, and 18 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention is directed to an apparatus for deployment of a hemostatic clip comprising a handle assembly, a shaft connected to a distal portion thereof and a clip assembly releasably coupled to a distal portion of the shaft. (*Specification*, ¶¶ [0038]-[0039],

Fig. 1). The clip assembly includes clip arms and a capsule cooperating with the clip arms to provide a first user feedback indicating a decision configuration of the clip assembly. (*Id.* at ¶ [0054]). In addition, the apparatus includes a control wire including a ball connector. (*Id.* at ¶ [0040]). The control wire extends from the handle assembly and is coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft. The ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft. (*Id.* at ¶ [0056]).

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1, 2, 4-5, and 15 are unpatentable under 35 U.S.C. § 102(a) as anticipated by U.S. Patent Publication No. 2003/0069592 to Adams et al. (“Adams”).
- II. Whether claims 3, 10-11, and 17-18 are unpatentable under 35 U.S.C. § 103(a) as obvious over Adams in view of U.S. Patent No. 6,814,742 to Kimura et al. (“Kimura”).

7. Argument

I. The Rejection of Claims 1, 2, 4-5, and 15 Under 35 U.S.C. § 102(a) as Anticipated by U.S. Patent Publication No. 2003/0069592 to Adams et al. Should Be Reversed

A. The Examiner's Rejection

In the final Office Action, the Examiner rejected claims 1, 2, 4-5, and 15 under 35 U.S.C. § 102(a) as anticipated by Adams. (5/11/05 Office Action, p. 2-3).

Adams shows a medical device consisting of a handle, a sheath 1206 extending distally therefrom and a clip 1201 disposed at a distal end of the sheath 1206. A control wire 1207 extending within the sheath 1206 is connected at a proximal end to the handle and at a distal end to the clip 1201. As the control wire 1207 is drawn proximally through the sheath 1206, a ball 1202 at a distal end of the control wire 1207 pulls the clip 1201 proximally through an outer sleeve 1204, which is connected to the distal end of the sheath 1206. The clip 1201 is locked into place within the outer sleeve 1204 when socket tabs 1203 at a proximal end of the clip 1201 fit into cut-outs 1205 in the outer sleeve 1204. Simultaneously, the ball 1202 is released from the clip 1201. The outer sleeve 1204 is then disengaged from the sheath 1206 when the sheath 1206 is drawn proximally.

B. The Cited Patent Does Not Disclose an Apparatus for Deployment of a
 Hemostatic Clip as Recited in Claims 1, 2, 4-5, and 15

Claim 1 recites an apparatus for deployment of a hemostatic clip comprising “a handle assembly” and “a shaft connected to a distal portion of the handle assembly” in combination with “a clip assembly releasably coupled to a distal portion of the shaft, the clip assembly including clip arms and a capsule cooperating with the clip arms *to provide a first user feedback indicating a decision configuration of the clip assembly*” and “a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly *to provide a second user feedback indicating separation of the clip assembly from the shaft.*”

Adams nowhere discloses that a user feedback is provided by the clipping device or the components thereof. Adams at best merely states that the user receives feedback regarding operation of the device due to optical components of the endoscope, which houses the device. That is, “[t]he success or failure of the application of pressure can be reviewed through the optical components provided separately in the endoscope.” (*Adams*, ¶ [0102]). Accordingly, Adams fails to teach or suggest wherein a “clip assembly including clip arms and a capsule cooperating with the clip arms” provides a user feedback, or wherein “ball connector is

detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft,” as recited in claim 1.

Further, Adams states, “when the sheath 1206 is pulled back through the working channel (not shown) of the endoscope (not shown), the outer sleeve 1204 will release with the clip 1201.” (*Adams*, ¶ [0084]). At this point, the ball 1202 has already been separated from the clip 1201 and cannot therefore provide any indication to a user that the clip 1201 has been separated from the shaft 1206. Specifically, when the control wire 1207 is pulled proximally, the clip 1201 is drawn proximally through the sleeve 1204 until the tabs 1203 reach the cut-outs 1205. At this point, the bias of the clip 1201 causes the socket tabs 1203 of the clip 1201 to move outward into the cut-outs 1205 clamping the arms of the clip 1201 shut. As the socket tabs 1203 move apart, the ball 1202 is released from the clip 1201 as shown in Fig. 12b. At this point the clip 1201 and the outer sleeve 1204 are still coupled to the sheath 1206. It is only after the release of the ball 1202 -- i.e., when tissue is clamped by the arms of the clip 1201 -- that the clip 1201 is ready to be separated from the sheath 1206. The user then pulls the sheath 1206 back through the working channel of the endoscope to separate the outer sleeve 1204 from the sheath 1206, thereby releasing the clip 1201 from the sheath 1206. Thus, any feedback a user gets from the ball 1202 is prior to the release of the clip from the shaft.

It is therefore respectfully submitted that Adams fails to disclose or suggest “a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft,” as recited in claim 1. Therefore, Applicants respectfully request that the rejection of claim 1 be withdrawn. Because claims 2, 4, 5 and 15 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claims 6 - 9, 12 - 14, 16 and 19 - 27 stand objected to as dependent upon a rejected base claim. In view of the above remarks concerning the allowability of the claims from which these claims depend, it is respectfully submitted that these claims are in condition for allowance.

II. The Rejection of Claims 3, 10-11, and 17-18 Under 35 U.S.C. § 103(a) as Obvious over Adams in view of U.S. Patent No. 6,814,742 to Kimura et al. Should Be Reversed

A. The Examiner's Rejection

In the final Office Action, the Examiner rejected claims 3, 10-11, and 17-18 under 35 U.S.C. § 103(a) as obvious over Adams in view of Kimura. (5/11/05 Office Action, p. 4-5).

The invention of Adams has been described above. Kimura discloses a physiological tissue clipping apparatus comprising a clip housed in an introducing tube, and a manipulating member. (Kimura, col. 4, lines 10-18).

B. The Cited Patents Do Not Overcome the Deficiencies Discussed Above with Regard to Claim 1, from which Claims 3, 10-11, and 17-18 Depend

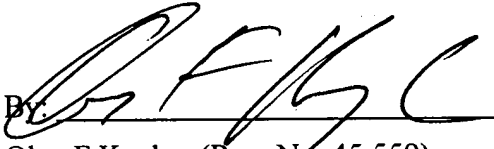
The deficiencies of Adams have been discussed above, and it is respectfully submitted that Kimura does not cure these deficiencies. That is, Kimura does not disclose or suggest “a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, *wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft,*” as recited in claim 1. Thus, because claims 3, 10-11, and 17-18 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable for at least the reasons stated above in regard to claim 1.

8. Conclusions

For the reasons set forth above, Appellant respectfully requests that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. §§ 102(a) and 103(a) and indicate that claims 1-5, 10, 11, 15, 17, and 18 are allowable.

Respectfully submitted,

Date: 11/3/05

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CLAIMS APPENDIX

1. Apparatus for deployment of a hemostatic clip comprising:
 - a handle assembly;
 - a shaft connected to a distal portion of the handle assembly;
 - a clip assembly releasably coupled to a distal portion of the shaft, the clip assembly including clip arms and a capsule cooperating with the clip arms to provide a first user feedback indicating a decision configuration of the clip assembly; and
 - a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft.
2. The apparatus according to claim 1, further comprising an over sheath movable between a first position covering the shaft and the clip assembly and a second position uncovering the clip assembly.
3. The apparatus according to claim 2, further comprising an over sheath stop engageable on the shaft to prevent movement of the over sheath to the second position.

4. The apparatus according to claim 1, wherein the clip arms further comprise stop shoulders engaging a distal end of the capsule to provide the first user feedback during proximal movement of the control wire.
5. The apparatus according to claim 1, wherein the decision configuration indicates a position of the control wire beyond which further proximal movement of the control wire precludes return of the clip arms to an open configuration by a reversed movement of the control wire.
10. The apparatus according to claim 9, wherein the separation tension is at least approximately 4 lbf.
11. The apparatus according to claim 9, wherein the separation tension is less than approximately 12 lbf.
15. The apparatus according to claim 1, wherein the first feedback includes a tactile and aural feedback.

17. The apparatus according to claim 16, wherein the yield tension is greater than the separation tension.
18. The apparatus according to claim 16, wherein the yield tension is between approximately 10 lbf and 20 lbf.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.